Industry HEAL thyself

JULY 1, 2002, THE RULES CHANGED. PhRMA's new Code

of Interactions with Healthcare Professionals, which outlines

ethical conduct between sales reps and healthcare professionals,

is being embraced by all stakeholders.

The new code is comprehensive and leaves very little room for interpretation. Developed by CEOs of the leading pharmaceutical companies, the guidelines eliminate the non-medically related programs and give-aways that have been used by the industry to gain access to physicians. The goal of the voluntary marketing code is to eliminate the abuses by a few, portray the industry as a whole in a more favorable light, and add value to the sales rep-physician relationship.

The right **MEDICINE**

TREWHITT. More than a year ago, key members of PhRMA's executive board identified that there was a need to revisit the guidelines and make some improvements to eliminate the periodic complaints and allegations about the practices of sales representatives and their relationships with doctors. These new comprehensive marketing guidelines went into effect July 1st. When we compared the new guidelines with the old guidelines, which had been in place since 1990, we added more specificity, clarity, and precision. There now is less room for interpretation. One of the key sections of the guidelines deems that sporting events and theater tickets are inappropriate. This includes everything from golf to sitting on the third baseline at Wrigley Field in Chicago watching the Giants play the Cubs. The goal of these guidelines is to make sure that there is a meaningful conversation between a sales representative and a physician about a new medicine and its potential value and characteristics, including potential side effects. Anything that distracts from a meaningful conversation about a drug is considered to be inappropriate. Anybody who makes a pitch or discusses a drug in any shape or form with doctors is technically considered to be a member of the sales team.

FRANKS. The reality is that corporate executives have come under intense scrutiny in recent months. In too many cases, certain American business leaders, accounting firms, and financial analysts have been dishonest in their communications with the American public. Against this backdrop, the development of a new marketing code of ethics was entirely appropriate to address the public's concerns. The new guidelines address the most important issues that confront healthcare professionals. We will need to carefully monitor the implementation of the new code to identify areas where further work may need to be done.

If the guidelines are to be fully realized, the SALES REPRESENTATIVE WILL BECOME MORE OF AN EDUCATIONAL RESOURCE to the physician office.



DAWES. The industry had been using guidelines established by the AMA in the 1990s. We felt that as an industry we should have our own guidelines, ones that we as an industry developed. Who knows our industry better than we do? These internally developed guidelines have the commitment of the industry's top-level CEOs, so there should be buy-in through the ranks of the companies.

FRANKS. It's important to recognize that for more than a year and a half, PhRMA has been looking into the issue of potential abuses in these relationships. Voluntarily, PhRMA took it upon itself to evaluate the old guidelines and identified the need to come up with a comprehensive new code. No one imposed this code on the industry; the new code was driven from the top down. I give our industry leadership credit for recognizing the need to take this issue on strongly, and in a very transparent manner. It's the type of step that can help to restore confidence both in our specific companies as well as in American business generally. The American public should know that this industry has voluntarily, and unanimously, adopted a new marketing code that governs relationships with healthcare professionals.

COX. The guidelines were necessary because the ethics of all companies are under question now. The pharmaceutical industry is under continuous scrutiny. Even its icons and paragons of virtue are being called into question. Given this climate, I applaud the industry for being proactive and demonstrating that



the issue of ethics is important. Actions in the public interest help the industry appear more positive in the eyes of all its important audiences.

TREWHITT. One of the goals of the code is to show the overwhelming value of the relationship between sales reps and doctors, and to do that we are making a good-faith effort to get rid of occasional, periodic violations of the guidelines. There is another reason the guidelines are important and urgent. While we believe very strongly that in the vast majority of cases the relationship already is proper and constructive, there is a perception among too many people that violations are the norm. This has led to an overreaction and we need

THE EXAMINATION ROOM ...

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to stop this overreaction from continuing. There are a smattering of hospitals and health clinics around the country that are putting in place draconian procedures restricting sales representatives from gaining access to physicians and nurse practitioners. Some institutions have even gone so far as to charge representatives, and in a year from now they won't even let the reps in.

PANTELLO. It was very important for PhRMA to address this issue. The transparent abuses by some companies — the dine-and-dash and gas-and-go activities — that were being reported in the press were hurting the image of the pharmaceutical industry, and this needed to be stopped. Further, these types of promotional activities encourage legislation that could negatively affect our industry.

GIEGERICH. Unfortunately, the guidelines were necessary. Not because the whole indus-



These internally developed guidelines have the commitment of the industry's top-level CEOs, so **THERE SHOULD BE BUY-IN THROUGH THE RANKS** of the companies. The guidelines were the **RIGHT THING TO DO**, but they were **LATE IN COMING**. The intensity of the scrutiny already was at a fevered pitch.

try was bad — most manufacturers already were adhering to internal guidelines — but there were enough exceptions to make this necessary. It's unfortunate that the industry had to come out and issue a bold proclamation that it was going to be ethical; it makes it sound to the uninvolved person that the industry has been unethical, which isn't true. The guidelines were the right thing to do, but they were late in coming. The intensity of the scrutiny already was at a fevered pitch.

MURATORE. The barbarians are already at the gate. The code is absolutely necessary. But it would have been better if the guidelines had been released a year ago or even earlier.

> **PERLOTTO.** Pharmaceutical promotion goes through cycles, and I think this is another one of those regulatory cycles that has been brought down upon the industry. The code pushes the pendulum back a bit.

> MILLIGAN. We are preparing to launch our first product, and the code was very welcomed by us. It evens the playing field for small companies. We can't spend the kind of money that larger companies can so the code gives us a chance to operate in a way that's consistent with our principles and allows us to be very successful and effective with physicians. When our reps launch our first product, everything we do will be consistent with a highly ethical and principled company. We wouldn't want to be the company that the physician could call to get tickets to the latest play.

BRENNAN. The guidelines level the playing field and they will help the representative bring more focus to the science of a product. Compliance to the guidelines will allow representatives and companies to be more science-oriented and more evidence-oriented and really help the doctor make decisions on patient cases and scenarios in crowd-ed markets.



MITZEN. Larger companies, which have been under the microscope with respect to pricing and marketing initiatives, will be more committed to the guidelines' tenets on entertainment, educational programs, gift giving, and dinner programs than perhaps some of the small- to medium-size companies. Some of these smaller companies may look at this as an opportunity to get a leg up and try to get time with those physicians that in the past they've had difficulty reaching because the larger firms have been cannibalizing all of the physicians' interest.

GIEGERICH. Competition is so intense and the pressure on any public company to achieve short-term results, even at the expense of ethical boundaries, is everywhere. The pharmaceutical industry is not immune to these pressures. The decisions that get made every day are important, and sometimes people dance on the line of what's right and wrong.

PERLOTTO. This type of action tends to provide fodder for the media, more than anything else. The timing, unfortunately, was tied to drug costs in the news again, so it was another outlet for the media to jump in and use a few examples as a stick to beat the industry as a whole.

TORROELLA. I would say the guidelines are absolutely necessary for a number of reasons. One, to prevent further negative perception and negative press. Two, it's the right thing to do in terms of the current pharmaceutical environment — numerous patent expirations, FDA approval delays, etc. The pharmaceutical industry as a whole is under tremendous financial pressure. I would estimate that the voluntary code will save more than \$1 billion per

year in expenses. Companies can either save this money, or to my third point, put it to even better use, which is to create a win-win for everyone. If companies divert this money to things that physicians and patients value more education — the relationships with physicians will be enhanced. In addition, compliance will be enhanced.

MITZEN. Many companies, in my opinion, have operated above board with respect to entertainment and gift giving and treating their customers like customers without creating a perception of buying business. On the other hand, the industry created its own monster because physicians came to expect these types of events. We were stuck in a viscous cycle. The rep couldn't get the attention of a physician unless he or she out did last year's event. The industry did itself a favor by adopting these codes.



THE BARBARIANS ARE ALREADY AT THE GATE.

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A dose of **REALITY**

MILLIGAN. The code is so much more respectful of the representatives' role than what has been allowed previously. For example, the idea of the "gas-and-go" is demeaning to a representative. The code brings the rep's The pharmaceutical industry is **UNDER CONTINUOUS SCRUTINY**. Even its icons and paragons of virtue are being called into question. Given this climate, I applaud the industry for being proactive and demonstrating that the issue of ethics is important.

role back to where it should be — adding value in a way that's not demeaning to the field force and not compromising to doctors. We all are in a better place now.

PERLOTTO. It's an interesting conundrum for physicians. Most physicians say they would never be swayed by such activities. But if we available up to it is that companies get

examine why it is that companies got into this arena, it's been to gain more access to physicians. Entertainment was being driven by the fact that reps couldn't get access to the physicians to do their jobs and to educate doctors. I don't think these activities grew out of a desire to go to a ball game or a play, but to gain access to physicians. For reps to fulfill their educational role, physicians have to provide the time and access. If the physicians were too busy to do that during business hours, then quite naturally the rep was going to look for a venue that had entertainment value to compensate for the physician's time while out of the office.

BRENNAN. Four or five years ago, there were 30,000 or 40,000 drug reps, now the number could be as high as 80,000 or 90,000. Because of the growth of the marketplace, access, length of call, and selling time are being compromised. What this filters down to is that representatives really need to know how to go in and truly understand the physician and his or her practice. Some representatives used entertainment as a selling lever, as an intro into a physician, but this is now gone, thus creating a void. Now reps, more than ever need to be able to bring value to the physicians. One of the ways they can bring value is to truly engage physicians about their practice, about their patient types, about the disease states. Reps need to provide physicians with information that can help them make better decisions. Reps need to provide compelling information to effect change,

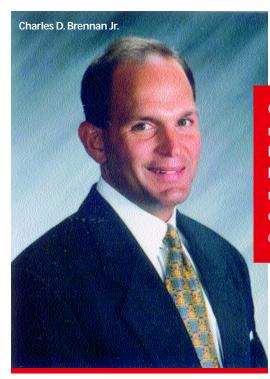


Teri Cox

but the only way they can get that information out is to engage the physician in a peer-to-peer discussion. They need to share knowledge, engage, and initiate a discussion from a platform of good questions, and then bring in the data. The other key is to carry the conversation. The rep may ask a good question, and the doc may give a great answer, but the rep doesn't know where to go from there. That's why clinical expertise is important.

GIEGERICH. The volume of sales representatives in the field right now is not matched with the market demand for those sales reps. That's not to say it wasn't matched five years ago. Today, in total there are simply too many reps in the field compared with what's in the pipeline and the introduction flow of new therapies. As manufacturers come to that realization in their own portfolios, they will have to reconsider the use of other channels to reach and influence doctors, and reach and influence patients. There's going to be a natural evolution from the traditional equation: more reps equals more calls, which equals more coverage, which equals more prescribing. This equation will change, there just isn't enough innovation to support this many reps in the field, and other media can pick up some of the slack.

MARCHICA. I wouldn't say the guidelines were necessary, per se. I think they were a reaction to the physician community throwing its hands up at being over-promoted to. The primary problem is that, over time, pharmaceutical companies have doubled, tripled, and quadrupled salesforces to the point where doctors have said, "enough." As companies continued to pound physicians with larger salesforces and mirrored territories, the focus on delivering value to the physician — the cus-



tomer — was lost. The only way to go back to a very science-based salesforce is by doing severe headcount cuts. It's very difficult for a representative today to have a meaningful conversation with a physician. It's the old baseball game analogy. If you sit in the bleachers and stand up because you decide you want a better view, for a while you're better off, but when everybody else stands up to watch the game, then nobody has a better view and everybody is worse off. Over the past five to 10 years, companies have continued to up the ante to the point where the total number of reps has doubled, but details are only up 5%.

GIEGERICH. There will be a gradual downsizing of the number of reps, and there will be a stratification of the reps. There will be a higher-level field force that is much more scientifically credible, almost at a peer-to-peer level, in essence a medical science liaison. These reps will deal with real, clinical-level substance data, serving almost as counselors to the prescribing world. This implies a much more credentialed, clinical relationship. In the past 50 years this has become muddled with the world of overt promotion. These medical liaison-type reps will coexist alongside another field force of promotional support representatives, who will not be expected to make calls on doctors or deliver clinical information. They will be there to service offices, organize community outreach programs, distribute samples and patient-support literature, and enroll patients in therapeutic programs.

MUMM. While I think the industry, as a whole, is very ethical, I think we're all aware that there have been some excesses on both

Compliance to the guidelines will allow representatives and companies to **BE MORE SCIENCE-ORIENTED AND MORE EVIDENCE-ORIENTED** and really help the doctor make decisions on patient cases and scenarios in crowded markets.

sides of the pharma/physician relationship. The new code should hopefully help to reinforce that the goal of collaboration between pharma and physicians is medical education and information for better patient care. The guidelines should bring back this focus.

COX. There might be different levels of sales reps. I can envision reps providing different

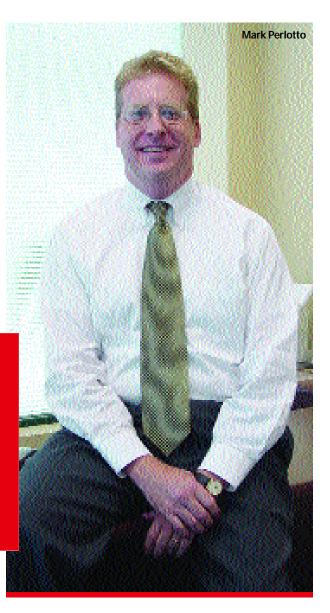
levels of information and being trained differently. Also, the qualifications for those reps would vary. We might start seeing more reps with professional provider backgrounds, such as physician assistants, nurses, and even physicians who change careers.

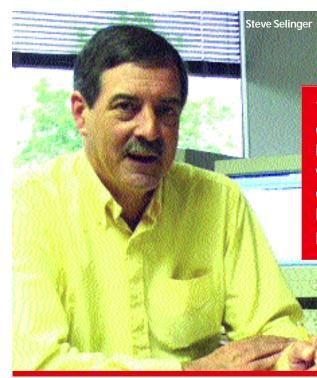
DAWES. Pharmaceutical presentations to physicians are built upon a scientific platform. When representatives go to physician offices, they talk about the science of their products. They explain what the product does, its medical benefits, how it works versus the other products, and what benefit it might have to a patient. At the end of the day, this is the value the representative can bring to healthcare professionals in the office.

It's an interesting conundrum for physicians. Most physicians say they would never be swayed by such activities. But if we examine WHY IT IS THAT COMPANIES GOT INTO THIS ARENA, IT'S BEEN TO GAIN MORE ACCESS TO PHYSICIANS. **SELINGER**. Physicians still will interact with pharmaceutical sales representatives. The personal sales call remains one of the most effective ways to communicate product information — especially for new products. Physicians have, sometimes grudgingly, acknowledged the value of a trained and knowledgeable salesforce. The promotional programs attendant to sales calls have always been designed to improve access, heighten awareness, and sustain message recall. These goals will not change, but to the extent that previous promotional activities fall outside of the new guidelines, the tactics used to achieve them will need to evolve to meet the new circumstances.

A physician CHECK-UP

TREWHITT. The American Medical Association's weekly newspaper, AM News, ran an article supportive of PhRMA for taking this





step. The feedback we've received from other doctors and physician groups also is complimentary.

TORROELLA. It's interesting to hear what physicians aren't saying as much as what they are saying. From practicing physicians, we're hearing mixed reactions. We're hearing, "I'm offended that people think I could be bribed," to "I haven't even heard about the code," to "This is the best thing in the world." I've heard from general practicing physicians that they will not be going to local meetings as much. They've said if their spouse can't come, they won't go. Of everything in the pharma code, which I think is excellent, this is the one thing that didn't have to be included. Flying a spouse to Palm Springs is another story. But buying a spouse a \$20 dinner in Lancaster, Pa., before a physician meeting is not extreme.

MILLIGAN. For medical advisory board meetings or speaker's training programs, companies will have to figure out how to include physicians' spouses without paying for them. Companies would be happy to pay for meals for the family member, but it's not allowed any more. These are some of the complexities that companies will need to navigate.

MUMM. I've heard mixed responses — some physicians applaud the guidelines. They see this as way of normalizing the situation on both sides. Other physicians said the guidelines were unnecessary — that their prescribing habits and decisions are based on the best interests of their patients and could not be influenced by a nice dinner.

The guidelines may help to blunt some of **THE CRITICISM THAT HAS BEEN LEVELED ALREADY**, but if legislatures want to make this an issue, no amount of self-regulation will satisfy those who believe that all forms of promotion are pernicious.

DAWES. I think most physicians want to receive the educational materials our companies and representatives can provide for their practices and patients. I think physicians will still go to events outside the office if they feel that the events are valuable from an educational point of view. I'm sure that there are a few physicians who will miss going to a sporting event, but, in general, I believe that the medical community supports what we are doing.

PANTELLO. Because the associated entertainment with meetings has been curtailed, this could potentially make it less attractive for physicians to attend events. For the long term, this code will bring activities back to normalcy. Physicians will adjust, companies will adjust, and we'll be paying attention to the right things. We'll be spending money the right way, rather than doing things that devalue the pharmaceutical sales representative/ physician relationship. The sales rep shouldn't have to buy gasoline for a physician to gain access to him. They should gain access to the physician because of the intellectual capital and the services they bring to the customer. This code will help re-establish the image of the sales rep with the physician.

When our reps launch our first product, EVERYTHING WE DO WILL BE CONSISTENT WITH A HIGHLY ETHICAL AND PRINCIPLED COMPANY. We wouldn't want to be the company that the physician could call to get tickets to the latest play.

MURATORE. We hear the bashing that comes from the physician societies about the

pharmaceutical industry, and all the evil things that we do, but at the same time, some physicians believe they deserve all the perks.

SELINGER. During a seminar at the American College of Physicians, one physician hoped that the new guidelines would not cover textbooks since her department has become increasingly reliant on sales reps to maintain their library. Others on the panel acknowledged that they appreciated pens, pads, etc. All claimed to be uninfluenced by any promotional activity, but all agreed that reps can provide useful information in the form of reprints, handouts, patient education, etc.

DIAGNOSING the impact

FRANKS. By defining expectations, and not just for sales representatives, but for physicians and other healthcare professionals, I think a great burden will be lifted from the healthcare industry as a whole.

MARCHICA. Everybody that I talk to these days is very, very sensitive to the new guidelines — all the way through the organization. Companies aren't just paying lip-service to the guidelines, which initially is what I thought would happen.



TREWHITT. The hope is that there will be a meaningful conversation, with the understanding that the physician controls the meeting. There have been two common approaches over the years, with some obvious exceptions. The first scenario is the physician who says, "you've got 10 minutes — make it good and emphasize technical points that are of value to me." That company sales representative is lucky if he or she gets a cup of coffee. They have to make a very well-organized 10- to 15minute presentation. The second common approach is

for a sales representative to go into a medical clinic to meet with the healthcare professionals, not only the doctors but the physician assistants and the nurse practitioners, and have an informal 30- or 45- minute lunch. It's within the guidelines for sales representatives to bring in a meal of modest cost. They certainly aren't going to buy a doctor's soul for the price of a sandwich or a pizza. During this time, the representative can have a meaningful conversation about the new medicine their company has just brought to the market. This has to be a conversation about the medicine and its potential value and what its potential side effects might be. That's a very common approach and is considered to be a constructive and proper meeting. This can't be a dine-and-dash event where the representative goes with the physician to a carry-out restaurant and, even though it's a modest meal, has a hurried conversation in a noisy environment. This is not appropriate.

DAWES. I don't think there will be more limited access to doctors. The outside office activities that we focus on with physicians are generally educational, and these activities will continue. The guidelines say some of the forms of "entertainment" that went with the education are no longer appropriate. I think companies will find ways to provide outside education within the guidelines.

MITZEN. The guidelines, I expect, will take pressure off the salesforces with respect to trying to get time with the physicians and competing with each other. The code strips everything back down to what the relationship



should be, which is the science, the features, and the benefits of the products as opposed to dinner cruises.

It's **IMPORTANT THAT WE POLICE OURSELVES** and do the right thing to avoid any type of overreaction that would encourage excessive and abusive legislation against our industry.

DAWES. Companies will need to be more

creative and there are plenty of ways to provide information and education over the Internet and through audio/visual opportunities. In terms of total spend, I would expect marketing executives will take a hard look at the promotional mix within the new guidelines.

PERLOTTO. Marketing managers will be looking at other promotional vehicles, such as promotional direct mail or deeper educational mail through supplements and symposium — there will be an increase in that activity again. For the more complicated drugs, there will be an increased investment in medical education — print medical education as well as online education.

TORROELLA. I think we'll see more use of the Web, audio conferences, and Webcasting. These are tactics that are being used now, but the percentage of their use will increase. Also, visiting faculty programs, where a thought leader is brought to the physician's office at lunch time or at the end of the day. Pharma companies are so fearful that they will have reduced access to physicians, but the question is, what was the access at a ball game or at a spa? What was the real ROI on those activities? I think it's questionable.

COX. Every company will need to be more creative about their marketing and sales approach. They will need to think through their programs more thoroughly. Their public relations, advertising, and CME partners also will have to consider public perceptions in their design of the programs they propose. Mutual benefit should be an important consideration.

MARCHICA. Some dollars will be shifted from some of the more traditional promotional and branding tactics and the relationshipbuilding focus will become more educational. If the guidelines are to be fully realized, the sales representative will become more of an

educational resource to the physician office. To achieve this, reps need to understand what physicians perceive as true educational value. And by delivering true value, reps will establish relationships that are built on trust.

TORROELLA. It won't be business as usual, where we expect all physicians to attend different events. We

need to find ways to bring education to physicians, so they don't have to leave their offices. Physicians will go out, but only if the event contains very compelling content and compelling speakers, which is a good thing, because this will force everyone to kick the content up a notch.

MITZEN. The days of giving away golf balls and other give-aways have been diminishing over time. We're going to have to come up with unique, different types of programs and ways to get the physician's attention, but that's what they are paying us for.

GIEGERICH. There will be more centralized control over marketing expenses. In that sense the guidelines benefit agencies and medical education companies and all the different communication suppliers. Over the years, a lot of those funds had been increasingly parceled to the field, where reps were allowed to spend money at their discretion and in places that sometimes were outside the bounds. Company headquarters — and as a result, communications agencies — will now be more centrally involved in the expenditure and development of field-rep programs, as well as alternatives. We'll see a shift toward more permissionbased versus intrusion-based types of marketing. The physician will have a need for information or the need for support or service, and they will dictate the terms of the engagement. There's business in there for agencies, because creating that shift from intrusion to permission is a very creative challenge.

MURATORE. These guidelines should have an impact on other channels of communications, such as journal advertising, but it hasn't happened yet. There are plenty of data that sug-

gest journal advertising is the best frequency tool. There are plenty of other types of direct marketing that should be utilized. We are definitely trying to push different channels that we know can work. The last time guidelines were put in place, companies dramatically changed the way they did their educational programs and marketing programs. We're not hearing that same type of rigorous change.

MILLIGAN. Because some of the things that were being done to establish access and relationships aren't available to companies now,

Paradigm Shift or Business as Usual?

ILL DOCTORS MISS DINE-AND-DASH, GIVE-AWAY TICKETS TO SPORTS EVENTS, AND FREE TRIPS WITH THEIR SPOUSES TO FANCY RESORTS? Or will they be just as happy to talk about drug indications and side effects with pharmaceutical sales representatives in exchange for a medical text instead of free golf balls? The Pharmaceutical Research and Manufacturers of America (PhRMA), on behalf of 80 of the country's largest pharmaceutical and biotechnology companies, and the American Medical Association (AMA), representing about half of the 600,000 doctors, hope so.

When PhRMA's new Code of Interactions with Healthcare Professionals, which outlines ethical conduct between sales reps and healthcare professionals, took hold on July 1,2002, many of the glossy amenities that have paved the way for reps were shelved in favor of more medically relevant approaches. This voluntary marketing code declares: no more free lunches ... unless it includes (real) learning and PhRMA's members are listening. Medicalliance Inc., Columbia, Md., conducted a survey to gauge the industry's reaction.

THE CODE'S TENETS

The major points of the code are:

- Rep-doctor relationships should focus on scientific/education information that benefits patients and enhances the practice of medicine.
- Providing meals without a company representative's presence is not appropriate.
- Meals are okay if they are modest, the restaurant is conducive to discussion, and the rep is reviewing educational or scientific themes.
- Pharmaceutical companies should not cover the cost of travel, lodging, or meals for non-faculty (usually meaning spouse) attendees at company-sponsored programs.
- Reps may not treat healthcare professionals to the theater, concerts, or sporting events.
- No gifts should be valued at more than \$100, and all should benefit patient care.
- Events and gifts must be "conducive to providing scientific or educational information."
- "Token consulting or advisory arrangements should not be used to justify compensating healthcare professionals for their time, travel, lodging, and other out-of-pocket expenses."
- The code isn't completely new, it simply reinforces existing guidelines set by the AMA, explains Susan Torroella, president of Medicalliance, an independent medical education company.

Indeed, the code is really a stronger version of the AMA's gift-giving

companies will look for other ways to establish this connection. I don't think journal advertising will be affected, because that is messagebased more than access- and relationshipbased. I do think that medical education will have to increase, and I think e-marketing also may increase.

guidelines, created in 1990 and highlighted again last summer during a well-publicized campaign. Essentially, PhRMA's guidelines follow the AMA's, but Jeff Trewhitt, a PhRMA spokesperson, emphasizes that this code was developed independently, not through a collaboration with the AMA. The impetus, however, was complaints about reps' unethical behavior from the AMA and from individual healthcare professionals.

In particular, the AMA found the idea of paying for spouse involvement abhorrent, according to Mr. Trewhitt. The perception is that this is a bribe and that the physicians are being bought, he says.

PHYSICIAN REACTION

Not only were the majority of prescribers contacted for Medicalliance's report completely unaware that the code was going into effect, all were clearly offended by the suggestion that goodies entice them to prescribe products.

Edward Zebovitz, M.D., an oral and maxillofacial surgeon in solo practice, agrees, "I'm insulted by the idea that I can be bought."

"I know guys who don't own much that a rep didn't give them, but did it make a difference in their prescribing habits? I doubt it," says one orthopedic surgeon who has been a partner in a private practice for 27 years.

"Stuffed zebras? That's silly and it's not what makes me prescribe antibiotics," a pediatrician says.

All the healthcare professionals interviewed stated that their prescription patterns were based not upon getting season tickets from reps, but, rather, on their own understanding of what was best for their patients.

William Trombetta, Ph.D., professor of pharmaceutical marketing at the Erivan K. Haub School of Business, St. Joseph's University, the Center for Pharmaceutical Marketing Studies, in Philadelphia, agrees. "These guidelines don't amount to a hill of beans," he says. "Doctors are getting killed by high malpractice premiums, de-selection by managed-care companies, and cuts by Medicare. They don't care about dinners; they need true, valueadded programs."

Other physicians interviewed viewed the code as an opportunity "for representatives to finally spend money on what matters to me and my patients."

When asked about their needs, healthcare professionals never mentioned season tickets to games. Rather, they say they desire information to make the best decisions about the care of patients. Specifically, prescribers asked for reps who are responsive to requests for specific information about the products being detailed and more unbranded educational materials.

"What I really value is unbranded educational information for my patients," says Zhanna Kalikhman, M.D., an internist. "I would very much appreciate a sales representative who, instead of giving golf balls, would

MUMM. I think there will be an increase in the use of outside agencies for more medical education programs, both accredited and nonaccredited. Historically, at times when there has been greater scrutiny on promotional activities, there has been a higher demand for outsourcing of speaker bureau programming and management and other physician education initiatives. More of our pharmaceutical clients who don't usually outsource these types of programs are now seeking to do so. We know the rules, so we can ensure that the programs and services we provide to our clients comply with regulatory requirements and reinforce industry standards for sound business practices, such as appropriate expenditures per physician. We're able to track all of these data to ensure that all of the appropriate guidelines are being met. I also think there's going to be greater reliance on e-CME and creative distance learning programs that will cost-effectively take accredited education to physicians and allied healthcare professionals in their practice settings.



provide non-product-specific disease state information that I could use in my office."

The pharmaceutical industry as a whole is under tremendous financial pressure. I would estimate that the voluntary **CODE WILL SAVE MORE THAN \$1 BILLION PER YEAR** in expenses.

Asked about what this code means to physicians, Dr. Kalikhman adds, "As physicians, we get to

spend very little time with our spouses. If spouses can no longer attend a dinner meeting, physicians won't go. Audioconferences, in-office education, and online CME will be much more popular."

INDUSTRY REACTION

Other than healthcare professionals, those most directly impacted by the code's implementation are sales reps. Many in the drug industry are relieved to see their companies undertaking the new marketing vows. One Schering-Plough respiratory rep says, "Finally, I can compete on the merits of my products and not which spa or ball game is better than the other. As long as all companies comply, the playing field is finally level. We have great products and I would rather focus on describing their features and benefits. Plus, I will have more free time to spend with my family since I won't be arranging special events all the time."

"Flyers about dinner programs are now clearly labeled 'spouses cannot attend,' and it's about time we focus on education rather than socializing," a Bristol-Myers Squibb oncology rep says.

So, if industry and prescribers are seeking essentially the same outcomes, why is there so much anxiety about adhering to the code?

"PhRMA was concerned that marketing efforts directed to prescribers were being perceived by patients, the public, the FDA, and the AMA as unethical," says Donna Fucello, Medicalliance's director of continuing medical education.

Besides Peter Jennings' "Bitter Medicine: Pills, Profit and the Public

Health," which aired on ABC-TV News in late May, the media seem to have latched onto sour information about pharma companies. From the whistle blowing over TAP's Lupron, to the fuss over Pfizer's Neurontin, to the scandal at ImClone Systems, to the furor over blatant advertising at last month's American Psychiatric Association meeting, the media seem to be seeking out — and reporting on — the most negative aspects of the industry.

One senior pharmaceutical manager believes that pressure to adhere to the guidelines comes in part from the press' heightened sensitivity about the business of pharmaceuticals.

"My sense is that companies will be following the code," says David Snow, who has been AstraZeneca's group director of hypertension and heart failure since January 2001. "And besides, with 85,000 reps out there, how inconspicuous can they be?"

Ms. Torroella agrees, and believes that the industry is also trying to avoid future regulations of pharmaceutical marketing. She cites the following worrisome trends:

• In June, Vermont Governor Howard Dean signed a law requiring pharmaceutical companies to disclose the purpose and value of gifts of \$25 or more to healthcare professionals. Fines are steep for non-disclosure: \$10,000 per violation.

• Massachusetts may also require healthcare professionals to report to the state gifts and honoraria from pharmaceutical companies worth more than \$50 or risk a heavy fine. Reports would then be posted at www.massmedboard.org.

• A number of private practices, some quite large, have banned pharmaceutical marketing.

- Some physicians are charging sales reps for their time.
- University of Wisconsin Hospital has banned all free samples.

• Some HMOs have begun to talk about educating providers themselves, rather than allowing pharmaceutical reps to do so.

Over the next six months, Medicalliance will continue to survey pharmaceutical executives, product managers, marketers, educators, healthcare professionals, and sales reps, and will track and analyze competitive programs. As needs are revealed, existing services will be modified and new ones created to ensure that all services provide medically relevant value. To participate in the survey, please e-mail Jennifer Curtis at jcurtis@medicalliance.com.

Source: Medicalliance Inc., Columbia, Md. To view the entire report, "A White Paper Covering Physician and Industry Reaction to PhRMA's Marketing Code," written by Jennifer Keats Curtis, log on to Medicalliance's Website, medicalliance.com. The report was originally published June 28, 2002.

Darlene Mumm



COX. I think new technologies will permit the convenience of fewer on-site and more distance-learning programs. With distance learning, the location won't even be a factor. Online interactive educational programs will be more convenient for those physicians who can't make the trips to distant sites. Companies need to develop more creative collaborations with professional associations, patient groups, and caregiver groups to create programs to help educate consumers, patients, and care givers. These types of programs are not about gifts, they are about creating mutually beneficial partnerships for the ultimate benefit of patients and providing information about state-of-the-art therapies for a particular illness.

PERLOTTO. Some companies may look at DTC more seriously, thinking if they can't gain access to the physician they'll push on the other side of the system, which is the patient. But this is a costly way to circumvent the normal rep-doc interaction.

MARCHICA. Even with an ROI evaluation program in place, money was being spent lavishly, not just on the sales side but on the marketing side. Then late last year companies' budgets started getting hit pretty hard, so even before the guidelines, companies were put in a position to make tough choices. Companies will continue to look at where they are spending their money and determine where they can get the best return. Additionally, a lot of the dollars that are being affected by the guidelines are in the discretionary budgets of the sales rep or the district manager. It's not as if the brand is controlling how, at least at the micro level, the reps are spending their money. The question I think that is important, is how

The new code should hopefully help to **REINFORCE THAT THE GOAL** of collaboration between pharma and physicians is **MEDICAL EDUCATION** and information for better patient care.

much funding has been cut to the district? Is the sales rep's budget 50% of what it was before? Is it 10% of what it was before? Is it the same? And, if it is the same, how are reps going to be spending their money? Companies will look to tactics that are highly ethical, and that are less promotional in the way that we usually think of them. I think that's going to be true even of the journal ads that we see. Traditional promotion is going be more science-based than ever.

MITZEN. There's going to continue to be a drive for scientific meetings and symposia; CME value will continue to increase. The guidelines also will free up the companies to explore some unique marketing initiatives that they may not have had funding for before, such as e-health programs outcomes research initiatives.

COMPLIANCE and persistency

FRANKS. Ethical relationships with healthcare professionals are critical to our mission of helping patients. Companies and sales reps that choose to take a different approach ultimately will have their reputations and corporate bottom lines impacted by the court of public opinion. Physicians and consumers are sophisticated when it comes to business relationships. They will only want to partner with those companies that have proven to be ethical and forthright. For non-compliant companies, the ultimate penalty could be the loss of a profitable business relationship.

TREWHITT. We strongly believe that the court of public opinion, to a large degree, is going to regulate the guidelines. PhRMA has gone public with the code and we have been very overt in talking about the new guidelines. Our companies are matching our openness in their discussions about the guidelines. The public knows that PhRMA and its member companies have these new marketing guidelines, and the public is going to be watching to see if we follow through. We are encouraged that the code will be taken seriously by the

companies and their sales representatives because these are guidelines that started at the top and are now working their way down through the ranks. Members of the board of directors of PhRMA — the CEOs of major pharmaceutical and biotechnology companies — endorsed these guidelines without dissent.

PANTELLO. The voluntary aspect is the weakest part of the code, in that it's not enforceable, particularly with non-PhRMA members. However, to the best of my knowledge, and I'm probably as close to this as anyone, the PhRMA member companies are adhering to the guidelines and the enforcement of the code within big pharma is very clear.

DAWES. The CEOs of major pharmaceutical companies approved the guidelines. And these CEOs sit on the board of PhRMA, which meets regularly. I would expect that if a company had an egregious action that was against the guidelines this would come up at a PhRMA meeting. And the CEO of that company would be forced to explain to his CEO colleagues why this was happening. This is certainly one incentive to have people comply with the guidelines.

PANTELLO. It's important that we police ourselves and do the right thing to avoid any type of overreaction that would encourage excessive and abusive legislation against our industry. It was important for the pharmaceutical companies to take an ethical stand, and it's working. We'll have an adjustment period, everybody has to get used to the new code. That said, working within the code will allow the industry to continue its good work.

MURATORE. These are voluntary guidelines, and pharma has to do a better job at policing itself. For the pharmaceutical companies that don't comply and don't put compliance plans in place, there should be some penalty. There is a continual negative cycle. This is the third time that guidelines have been issued. We put initiatives in place because there has been a public backlash. People toe the line for a while, and then they start pushing the envelope, then



we are in an arms race again because physicians are all too willing to accept the perks.

TREWHITT. Out of necessity, these are voluntary guidelines. Our lawyers concluded that as a trade association of many different competing companies — about 80 — we could not put in place mandatory rules, for fear of antitrust concerns. Certainly key policy makers and critics of the industry know about the guidelines, and make no mistake, these policy makers and critics are going to be watching the implementation of these guidelines very carefully and very closely. Companies that don't abide by the guidelines, one would assume, will be sharply criticized.

MILLIGAN. Since Endeavor is not a PhRMA member we wouldn't have to adhere to the code, but we will. The code is very consistent with how we want to approach the marketplace. We are very glad that virtually all pharmaceutical companies will be following the guidelines.

COX. Those companies that fall short will be criticized. They will hear from the FDA if they go overboard. In the realm of public opinion,



I give our industry leadership credit for **RECOGNIZING THE NEED TO TAKE THIS ISSUE ON STRONGLY**, and in a very transparent manner.

those companies that play to high ethical standards will be rewarded and those that don't eventually will be punished.

MARCHICA. There's no way to legislate or litigate ethical behavior. Most of this will fall back on the FDA and how the agency reviews promotions and advertising. Every indication that I see is that companies are paying very close attention to the guidelines and are taking them very seriously. How long will this last, who knows?

TORROELLA. The reps are the ones who will be doing the policing. At this point in time, I am impressed by how seriously all the pharmaceutical companies and their sales reps are taking the guidelines. It may not be necessary to have a lot of policing. Just as with off-label promotion or inappropriate promotion, the ultimate policing agency is the FDA, but it's the sales reps who send on the inappropriate information.

SELINGER. Some companies will always be more conservative in their marketing activities than others. I think that peer pressure will probably be effective in prompting broad compliance with the new guidelines. The guidelines may help to blunt some of the criticism that has been leveled already, but if legislatures want to make this an issue, no amount of self-regulation will satisfy those who believe that all forms of promotion are pernicious.

TREWHITT. We think states moving forward with legislation will discover what we already know, that in the vast majority of cases the

The industry created its own monster because physicians came to expect these types of events. We were stuck in a viscous cycle. The **INDUSTRY DID ITSELF A FAVOR BY ADOPTING THESE CODES**.



relationship between sales representatives and physicians is not only appropriate but quite constructive.

FRANKS. N.J. Governor McGreevey has been an outspoken advocate of our research-based pharmaceutical industry. He knows that our industry helps to define the economic wellbeing of N.J. Governor McGreevey has championed our cause, at both the state and federal levels. New Jersey is the global epicenter of the pharmaceutical industry, which is the premiere industry of our state. Government interference would be disconcerting and not well received.

DAWES. Any legislative group, whether it be state or federal, would have to look favorably at the guideline initiative. These are stringent rules that we put in for the industry, and they reflect the spirit of the commercial leaders of the industry. The goal in our industry, and what we want to be known for, is to create innovative pharmaceuticals that save people's lives. As leaders in the industry, we are a bit concerned with the current manner in which the industry is being viewed.

PANTELLO. The industry has to be ever mindful, particularly as we move into the next legislative year that we do the right thing, and do it the right way. Most of us who have been in the industry a long time want to project our belief that patients come first. This industry is an integral part of the healthcare system, and all of our activities should be focused on the patient. ◆

PharmaVoice welcomes comments about this article. E-mail us at feedback@pharmalinx.com.